भारतीय मानक

Indian Standard

IS 1000 : 2021

खाने योग्य लैक्टोज़ — विशिष्टि

(दूसरा पुनरीक्षण)

Edible Lactose — Specification

(Second Revision)

ICS 67.100.01

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भारतीय मानक ब्यूरो
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June 2021 **Price Group 4**

Dairy Products and Equipment Sectional Committee, FAD 19

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Dairy Products and Equipment Sectional Committee had been approved by the Food and Agriculture Division Council.

Lactose is manufactured from the whey remaining after the manufacture of casein, cheese, *paneer* or *chhana* from milk.

This standard was published in 1959 and first revised in 1989 to bring the requirements in line with the International Codex Standard for Lactose.

The second revision has been undertaken to harmonize the standard with Codex Standard (CXS 212-1999) and FSSAI Regulations and the major changes include:

a) Modification of requirement of moisture and sulphated ash and addition of requirement for scorched particles.

b) Alignment of microbiological requirements as per the *Food Safety and Standards (Food Products Standards and Food Additives) Regulations*, 2011.

c) Inclusion of Kraft paper bags or plastic containers like PET and HDPE for packaging of edible lactose.

In the formulation of this standard, due consideration has been given to the *Food Safety and Standards Act*, 2006 and Regulations framed thereunder; the *Legal Metrology Act*, 2009 and Rules framed thereunder and the Essential Commodities Act, 1955. However, this standard is subject to restrictions imposed under these, wherever applicable.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding-off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

The composition of the Committee responsible for formulation of the standard is given in Annex E.

Indian Standard
EDIBLE LACTOSE — SPECIFICATION
(Second Revision)

1 SCOPE

This standard prescribes the requirements and the method of test for edible lactose. It does not cover lactose used in pharmaceutical formulations.

2 REFERENCES

The following standards listed below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS/ISO No.	*Title*
460 (Part 1) : 2020	Specification for test sieves: Part 1 Wire cloth test sieves (*fourth revision*)
1070 : 1992	Reagent grade water — Specification (*third revision*)
1479 (Part 2) : 1961	Methods of test for dairy industry: Part 2 Chemical analysis of milk
2491 : 2013	Food hygiene — General principles — Code of practice (*third revision*)
5401 (Part 1) : 2012/ISO 4832 : 2006	Microbiology — General guidance for enumeration of coliforms: Part 1 Colony count technique (*second revision*)
5403 : 1999	Method for yeast and mould count of foodstuffs (*first revision*)
5887	Methods for detection of bacteria responsible for food poisoning
(Part 1 : 1976)	Isolation, identification and enumeration of *Escherichia coli* (*first Revision*)
(Part 2) : 1976	Isolation, identification and enumeration of *Staphylococcus aureus* and faecal streptococci (*first revision*)
(Part 3) : 1999	General guidance on methods for the detection of *Salmonella* (*second revision*)
(Part 4) : 1999	Isolation, and identification of *Clostridium perfringens*, *Clostridium welchii* and *Clostridium botulinum* and enumeration of *Clostridium perfringens* (*second revision*)
10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
11078 : 2012	Round open top sanitary cans for milk powder — Specification (*second revision*)
11124 : 1984	Method for atomic absorption spectrophotometric determination of arsenic
12074 : 1987	Method for determination of lead by atomic absorption spectrophotometer
13500 : 1992	Spray dried milk powders — Scorched particles — Determination
14988 (Part 1) : 2020/ISO 11290-1 : 2017	Microbiology of food and feeding stuffs — Horizontal method for detection and enumeration of *Listeria monocytogenes*: Part 1 Detection method (*first revision*)
15279 : 2003	Sugar and sugar products — Methods of test
5402 (Part 1) : 2021/ISO 4833-1 : 2013	Microbiology of the food chain — Horizontal method for the enumeration of microorganisms: Part 1 Colony count at 30 °C by the pour plate technique (*third revision*)
ISO 12779 : 2011	Lactose — Determination of water content — Karl Fischer method
ISO 15213 : 2003	Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of sulfite reducing bacteria growing under anaerobic conditions

IS/ISO No.	*Title*
ISO 22662 : 2007	Milk and milk products — Determination of lactose content by high performance liquid chromatography (Reference method)
ISO 26462 : 2010	Milk — Determination of lactose content — Enzymatic method using difference in *p*H

3 REQUIREMENT

3.1 Description

Lactose is a disaccharide sugar found in milk. The material shall be obtained from the whey of milk of buffalo or cow or goat or sheep or camel or mixture thereof. It shall be in the form of a crystalline powder, white to light yellow in colour, slightly sweet, nearly odourless, free from dirt or other foreign matter.

3.2 Particle Size

The material shall pass through a 250 µm IS sieve [*see* IS 460 (Part 1)].

3.3 Hygienic Requirements

Lactose shall be manufactured and handled under strict hygienic conditions as prescribed in IS 2491.

3.4 The material shall also comply with the requirements given in Table 1 and Table 2.

3.5 The product may contain permitted food additives within the limits as specified under the *Food Safety and Standards (Food Products Standards and Food Additives) Regulations*, 2011.

Table 1 Requirements for Edible Lactose

(*Clause* 3.4)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Lactose (on dry basis), percent by mass, *Min*	99.0	ISO 22662 or ISO 26462
ii)	Water content, percent by mass, *Max*	6.0	ISO 12779
iii)	Sulphated ash (on dry basis), percent by mass, *Max*	0.3	10 of IS 15279 : 2003
iv)	*p*H (of 10 percent solution)	4.5-7.0	Annex A
v)	Specific rotation	52.0-52.6	Annex B
vi)	Nitrogen, percent by mass, *Max*	0.05	7 of IS 1479 (Part 2)
vii)	Arsenic (As), mg/kg, *Max*	1	IS 11124
viii)	Lead (Pb), mg/kg, *Max*	2	IS 12054
ix)	Scorched particle, mg/25 g, Max	15 (equivalent to Disc B)	IS 13500

Table 2 Microbiological Requirements for Edible lactose

(*Clause* 3.4)

Sl No.	Characteristic	Requirement				Method of test, Ref to
		Sampling Plan 1)		Limit (cfu)		
		n	c	m	M	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Aerobic plate count	5	2	3×10^4/ml	5×10^4/ml	IS 5402 (Part 1)
ii)	Coliform count	5	2	1/g	50/g	IS 5401 (Part 1)
iii)	*Staphylococcus aureus* (Coagulase positive)	5	2	10/g	1×10^2/g	IS 5887 (Part 2)
iv)	Yeast and Mould count	5	0	50/g	NA	IS 5403
v)	*Salmonella* sp.	5	0	Absent/25 g	NA	IS 5887 (Part 3)
vi)	*Listeria monocytogenes*	5	0	Absent/g	NA	14988 (Part 1)
vii)	*Bacillus cereus*	5	3	5×10^2/g	1×10^3/g	IS 5887 (Part 4)
viii)	*Sulphite reducing clostridia*	5	3	50/g	1×10^2/g	ISO 15213
ix)	*E. coli*	5	0	Absent/g	NA	IS 5887 (Part 1)

NOTE 1) For sampling plan see Annex C.

4 PACKING AND MARKING

4.1 Packing

4.1.1 *Retail Packing*

The product shall be packed in clean and sound metal containers (*see* IS 11078) or glass containers or inert plastic containers like PET and HDPE Jars or in a food grade flexible pack made from a film or combination of any of the substrates made of board, paper, polyethylene, polyester metalized film or aluminium foil in such a way so as to protect it from deterioration. In the case of the plastic material, only food grade plastic (*see* IS 10171) shall be used.

4.1.2 *Bulk Packing*

The product may be packed in quantities of 25 kg in bags of food grade polyethylene (*see* IS 10171) of minimum thickness 0.05 mm. The bags should be properly closed by sewing or heat sealing and shall be subsequently encased in multi-walled kraft paper, such as crepe kraft paper bags of not less than 80 g/m^2 (GSM) grade, appropriately lined and having two or more inner layers of plain kraft paper of not less than 80 g/m^2 (GSM) grade.

4.2 Marking

4.2.1 The following information shall be marked legibly and indelibly on each container:

a) Name of the material and brand name if any;
b) Name and address of the manufacturer;
c) Batch or code number;
d) Month and year of manufacturing or packing;
e) Net quantity;
f) Direction for storage;
g) Best before .... (month and year in capital letters);

OR

Best before .... (months) from the date of packing/manufacture; and

h) Any other requirements under the *Food Safety and Standards* (*Packaging and Labelling*) *Regulations*, 2011 and the *Legal Metrology Act*, 2009 and Rules framed thereunder.

4.2.2 *BIS Certification Marking*

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

5 SAMPLING

Representative samples of the product shall be drawn and tested for conformity to this standard as prescribed in Annex D.

6 TESTS

6.1 All the tests shall be carried out as specified in **3** and Table 1 and Table 2.

6.2 Quality of Reagents

Unless specified otherwise, pure chemicals shall be employed in tests and distilled water (*see* IS 1070) shall be used where the use of water as reagent is intended.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the test results.

ANNEX A

[*Clause* 3.4, *Table* 1, *Sl No.* (iv)]

DETERMINATION OF *p*H

A-1 GENERAL

The *p*H of the edible lactose is determined with a *p*H meter.

A-2 APPARATUS

A-2.1 *p*H Meter, capable of reading with an accuracy of ± 0.01.

A-3 REAGENTS

A-3.1 Water

A-3.2 Buffer Solutions

A-4 PROCEDURE

A-4.1 Standardize the *p*H meter with suitable buffer solution. Rinse the electrodes with distilled water and leave for 5 minutes.

A-4.2 Measure the *p*H of 10 percent solution of lactose by immersing the electrodes in the solution and taking the reading after 5 min.

A-4.3 Express the result as pH to the nearest 0.01 *p*H.

ANNEX B

[*Clause* 3.4, *Table* 1, *Sl No.* (v)]

DETERMINATION OF SPECIFIC ROTATION

B-1 PROCEDURE

Accurately weigh 10.00 g of the sample and dissolve it in a beaker in about 60 ml water. Cover with a watch glass and boil for 15 min. Allow to cool, add a few drops of dilute ammonium hydroxide of specific gravity 0.96 and make up to 100 ml in a volumetric flask. Measure the optical rotation at 20 °C.

B-2 CALCULATION

B-2.1 Specific rotation, degree(s) = $\frac{100\,\mathrm{a}}{l\,c} \times \frac{100}{w}$

where

a = observed optical rotation, in degrees;

l = length of tube, in decimetres;

c = weight in g, of sample dissolved in 100 ml of water; and

w = percentage of lactose in the material.

ANNEX C

[*Table* 2]

SAMPLING PLAN FOR MICROBIOLOGICAL REQUIREMENTS

C-1 SAMPLING PLAN FOR MICROBIOLOGICAL REQUIREMENTS

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m for 2-class sampling plan and between m and M for 3-class sampling plan.

m = Microbiological limit that separates unsatisfactory from satisfactory in a 2-class sampling plan or acceptable from satisfactory in a 3-class sampling plan.

M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

C-2 INTERPRETATION OF RESULTS

2-Class Sampling Plan (where n, c and m are specified)	**3-Class Sampling Plan (where n, c, m and M are specified)**
1. Satisfactory, if all the values observed are ≤ m 2. Unsatisfactory, if one or more of the values observed are > m or more than c values are ≥ m	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M and the rest of the values are observed as < m 3. Unsatisfactory, if one or more of the values observed are > M or more than c values are ≥ m

ANNEX D

(*Clause* 5)

SAMPLING OF LACTOSE

D-1 GENERAL REQUIREMENT OF SAMPLING

In drawing, preparing, storing and handling samples, the following precautions and directions shall be observed.

D-1.1 Samples shall be taken in a protected place not exposed to damp air, dust or soot.

D-1.2 The sampling instruments shall be clean and dry when used.

D-1.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument, and the containers for samples, from adventitious contamination.

D-1.4 The samples shall be placed in clean and dry glass containers. The sample containers shall be of such a size that they are almost completely filled by the sample.

D-1.5 Each container shall be sealed air-tight after filling, and marked with full details of sampling, date of sampling, batch or code number, name of the manufacturer and other important particulars of the consignment.

D-1.6 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

D-1.7 Sampling shall be done by a person agreed to between the purchaser and the vendor, and in the presence of the purchaser (or his representative) and the vendor (or his representative).

D-2 SCALE OF SAMPLING

D-2.1 Lot

All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute the lot. If the consignment is declared to consist of different batches of manufacture, the batches shall be marked separately and the groups of containers in each batch shall constitute separate lots.

D-2.2 Gross Sample

For the purpose of drawing samples for tests, a number of containers shall be selected at random from a lot. This number of containers in relation to the size of the lot, or the scale of sampling, shall be subject to an agreement between the purchaser and the vendor. As a guide to such an agreement, a scale of the size of the sample is suggested in Table 3.

Table 3 Minimum Number of Containers to be selected for Sampling from Various Sizes of Lots

(*Clause* D-2.2)

Lot Size (1)	Sample Size (2)
2 to 8	2
9 to 27	3
28 to 64	4
65 to 125	5
126 to 216	6
217 to 343	7
344 to 512	8
513 to 729	9
730 to 1 000	10
1 001 to 1 331	11

D-3 TEST SAMPLES AND REFEREE SAMPLE

D-3.1 Preparation

To prepare a set of test samples, draw with an appropriate sampling instrument, from each container in the gross sample, not less than 0.75 kg of the material and mix thoroughly to form a composite sample of that container. Divide the composite sample of each container into three equal parts, each being a reduced sample for that container. A. set of such reduced samples, consisting of one reduced sample from each container, shall constitute the test sample.

D-3.2 Three sets of test samples, each sample being not less than 0.25 kg, shall be transferred immediately to thoroughly clean and dry containers, and sealed air-tight. These shall be labelled with particulars given in **D-1.5**. One set of test samples shall be sent to the purchaser and one to the vendor.

D-3.3 Referee Sample

The third set of test samples, bearing seals of the purchaser and the vendor, shall constitute the referee sample, to be used in case of dispute between the purchaser and the vendor. It shall be kept at a place agreed to between the purchaser and the vendor.

D-4 TEST FOR CONFORMITY

D-4.1 Examination and Tests

The purchaser may examine and test each of the reduced samples constituting a test sample separately for compliance with the requirements of this standard or he may prepare, for the purpose of such examination, and at any stage of the progress of the examination, a composite sample representative of the whole lot, by mixing all the reduced samples constituting the test sample.

D-4.2 Criterion for Conformity

If, on examination and testing, all the individual reduced samples in a test sample or the composite sample are found to comply with the requirements of this standard, the lot shall be considered to have conformed to this specification. If some of the individual reduced samples do not comply with the requirements of this standard and the results vary from one reduced sample to another, the criterion for judging the quality of lot on the basis of results obtained shall be at the discretion of the purchaser unless otherwise previously agreed to between the purchaser and the vendor.

ANNEX E

(*Foreword*)

COMMITTEE COMPOSITION

Dairy Products and Equipment Sectional committee, FAD 19

Organization	*Representative(s)*
National Dairy Research Institute, Karnal	Dr Manmohan Singh Chauhan (***Chairman***)
All India Food Processors Association, New Delhi	Dr K. L. Gaba Mr Vijay Gaur (*Alternate* I) Mr Santash Kumar (*Alternate* II)
Bihar State Cooperative Milk Producers' Federation Ltd, (COMPFED), Delhi	Mr Sushil Kumar Mr Rupesh Raj (*Alternate*)
CONCERT, Chennai	Mr K. Ramachandran Mr M. R. Krishnan (*Alternate*)
Confederation of Indian Food Trade & Industry, New Delhi	Ms Priyanka Gupta Dr Anirudha Chhonkar (*Alternate*)
Confederation of Indian Industry, New Delhi	Ms Neha Aggarwal Ms Arti Gupta (*Alternate*)
Centre for Analysis and Learning in Livestock and Food (CALF), Anand	Dr Rajesh Nair Dr Rajeev Chawla (*Alternate*)
Department of Animal Husbandry, Dairying & Fisheries, New Delhi	Mr Sagar Mehra Mr Rajesh Kumar Gupta (*Alternate*)
Directorate of Marketing and Inspection, Faridabad	Deputy Agricultural Marketing adviser Senior Marketing Officer-Standard (*Alternate*)
Export Inspection Council of India, New Delhi	Dr S. K. Saxena Mr Vikas Dahiya (*Alternate*)
Envirocare Labs Pvt Ltd, Thane	Mr Nilesh Amritkar Ms Sabeena K. (*Alternate* I) Ms Kavita Gokhale (*Alternate* II)
FICCI Research and Analysis Centre, New Delhi	Dr S. K. Manocha Dr Ajay Sharma (*Alternate*)
Food Safety and Standards Authority of India, New Delhi	Dr Monica Puniya Ms Tripti Tayal (*Alternate*)
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Haryana Dairy Development Coop Federation Ltd, Panchkula	Mr S. S. Kohli Mr Y. P. Singh (*Alternate*)
IDMC Ltd, Anand	Mr Devender Gupta Mr Prakash Maheshwari (*Alternate*)
Indian Dairy Association, New Delhi	Dr G. S. Rajorhia Dr Satish Kulkarni (*Alternate*)
Indian Stainless Steel Development Association, Gurugram	Mr Rohit Kumar Mr Rajat Aggarwal (*Alternate*)
Infant and Young Child Nutrition Council	Dr Nirupama Sharma Mr Kiran Desai (*Alternate*)
Jupitor Glass Works, New Delhi	Mr Karan Nangia Mr Amreek Singh Puri (*Alternate*)

Organization	*Representative(s)*
Mother Dairy Fruit and Vegetable Ltd, Delhi	Ms Nita Sen Mr Shailender Kumar (*Alternate*)
National Dairy Development Board, Anand	Dr R. S. Lahane Mr Suresh Pahadia (*Alternate*)
National Dairy Research Institute, Karnal	Dr Vivek Sharma Dr Rajesh Kumar Bajaj (*Alternate*)
National Institute of Food Technology Entrepreneurship & Management (NIFTEM), Sonipat	Dr P. K. Nema
National Institute of Nutrition, Hyderabad	Dr B. Santosh Kumar Dr Sylvia Fernandez Rao (*Alternate*)
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Punjab State Coop Milk Producers' Federation Limited	Dr Brar
Rajasthan Co-op Dairy Federation (RCDF) Ltd, Jaipur	Mr J. D. Singh
Tamil Nadu Co-op Milk Producers' Federation Limited, Chennai	Mr S. R. Sankar Mr T. M. James Dinakaran (*Alternate*)
Tetra Pak India Pvt Ltd, Pune	Mr Shashikant Ramnath Suruse Mr Sameer Singh Suhail (*Alternate*)
Vimta Labs Limited, Hyderabad	Dr Jagadeesh Kodali Dr Muni Nagendra Prasad Poola (*Alternate*)
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Dr Bhawana
Scientist 'D', BIS

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This Indian Standard has been developed from Doc No.: FAD 19 (16072).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Published by BIS, New Delhi